COMMISSION OF THE EUROPEAN COMMUNITIES

Brussels, 20/X/2004
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NOT FOR PUBLICATION

COMMISSION DECISION

of 20/X/2004

amending the marketing authorisation for "PegIntron - Peginterferon alfa-2b", a medicinal product for human use, granted by Decision C(2000)1407

(Text with EEA relevance)

ONLY THE FRENCH AND DUTCH TEXT ARE AUTHENTIC

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(Text with EEA relevance)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Council Regulation (EEC) No 2309/93 of 22 July 1993 laying down Community procedures for the authorization and supervision of medicinal products for human and veterinary use and establishing a European Agency for the Evaluation of Medicinal Products[1],

Having regard to Commission Regulation (EC) No 1085/2003 of 3 June 2003 concerning the examination of variations to the terms of a marketing authorisation for medicinal products for human use and veterinary medicinal products falling within the scope of Council Regulation (EEC) No 2309/93[2], and in particular Article 6(10) thereof,

Having regard to the application submitted by Schering Plough Europe on 16 July 2004 under Article 6(1) of Commission Regulation (EC) No 1085/2003,

Having regard to the opinion of the European Medicines Agency, formulated by the Committee for Medicinal Products for Human Use on 16 September 2004,

Whereas:

(1) An examination of the major variation type II to the terms of the marketing authorisation for the medicinal product "PegIntron - Peginterferon alfa-2b", entered in the Community register of medicinal products under Nos EU/1/00/131/001-050 and authorised by Commission Decision C(2000)1407 of 25 May 2000, has shown that the product still complies with the requirements set out in Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use[3].

[1] OJ L 214, 24.8.1993, p. 1. Regulation as amended by Commission Regulation (EC) No 649/98 (OJ L 88, 24.3.1998, p. 7).
[2] OJ L 159, 27.6.2003, p. 24.
[3] OJ L 311, 28.11.2001, p. 67. Directive as last amended by Directive 2003/63/EC (OJ L 159, 27.6.2003, p. 46).

(2) The application under Article 6(1) of Regulation (EC) No 1085/2003 to modify the marketing authorisation and to amend Decision C(2000)1407 accordingly should therefore be accepted.

(3) For the sake of clarity and transparency, it is advisable, following the amendment of part or parts of the annexes to a marketing authorisation, to provide for consolidated versions thereof. For this reason, a full set of annexes concerning the marketing authorisation for the medicinal product "PegIntron - Peginterferon alfa-2b" is attached to this decision.

HAS ADOPTED THIS DECISION:

Article 1

Decision C(2000)1407 is amended as follows:

1. Annex I is replaced by the text set out in Annex I to this Decision;

2. Annex III B is replaced by the text set out in Annex III B to this Decision.

Article 2

This Decision is addressed to Schering Plough Europe, Rue de Stalle, 73, 1180 Bruxelles, Belgique – Stallestraat, 73 – 1180 Brussel, België.

Done at Brussels, 20/X/2004

For the Commission
Olli REHN
Member of the Commission